

## **I. Remarks**

Claims 1-6 are currently pending.

Claims 1-5 have been amended by this response. Claims 1-4 have been amended to correct the spelling of the word "angiogenesis" where it had been inadvertently misspelled. Claims 1, 3, and 5 have also been amended to change the word "delivery" to the correct word "delivering" where it had been inadvertently misspelled. Claims 1, 3, and 5 have been amended without prejudice to delete the language which claims Claudin-7 fragments, biological equivalents, and derivatives for use in the instant methods. Applicant reserves the right to claim this subject matter in later continuing cases. Support for these amendments is found throughout the specification and particularly at page 2, lines 18-23; page 3, lines 3-8; page 7, lines 20-24; page 22, Example 2; and page 23, Example 3. As such, no new matter has been added by these amendments and Applicant respectfully requests their entry.

## **II. Priority**

The Office has alleged that the instant claims have priority only to August 7, 2000. Applicant respectfully traverses. The instant application properly claims priority to the Provisional patent application No. 60/147,752 filed on August 6, 1999. The '752 application discloses the subject matter of the instant claims.

The instant claims are drawn to methods that utilize a composition comprising Claudin-7 to modulate angiogenesis, endothelial cell proliferation, and tumor growth. Claudin-7's surprisingly high induction in both primary and metastatic tumors, as compared to normal tissue controls, was disclosed in the '751 application on page 10, lines 16-21 and on page 11, lines 17-18. Having identified Claudin-7 as an important protein in cancer cells, the '752 specification then discusses Claudin-7's potential role in modulating angiogenesis, endothelial cell function, and tumor growth (see page 13, line 12 to page 14, line 4.) Although Applicant was the first to identify Claudin-7's role in angiogenesis, endothelial cell proliferation, and tumor growth, the Claudin-7 gene had been cloned as of the writing of the '752 application (see page 13, lines 16-19.) Therefore, Applicant respectfully asserts that the instant claims do properly claim priority back to the disclosure provided in the '752 application.

## **III. Claim rejections under 35 U.S.C. § 112**

A) Claims 1-6 stand rejected under 35 U.S.C §112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant respectfully traverses. The amendments to the claims submitted with this response render this rejection moot. Claims 1, 3, and 5 have been amended to use the word "delivering" rather

than "delivery". Claims 1, 3, and 5 have been amended to remove the incorrectly used word "on" on line 2. Accordingly, Applicant respectfully requests withdrawal of this rejection.

B) Claims 1-6 stand rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant respectfully traverses.

As amended, the instant claims utilize a composition comprising Claudin-7 in methods for modulating angiogenesis, endothelial cell proliferation, and tumor growth. The nucleic acid and amino acid sequences of Claudin-7 are provided in the instant specification as SEQ ID NO:1 and SEQ ID NO:2, respectively. As noted by the Office in the Office Action mailed March 17, 2004, Claudin-7 meets the written description provision under 35 U.S.C. §112, first paragraph (page 4, first sentence.) Accordingly, Applicant respectfully requests withdrawal of this rejection.

C) Claims 1-6 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant respectfully traverses.

The instant claims utilize a composition comprising Claudin-7 in methods for modulating angiogenesis, endothelial cell proliferation, and tumor growth. The instant specification provided the nucleic acid and amino acid sequences of Claudin-7 as SEQ ID NO:1 and SEQ ID NO:2, respectively. Accordingly, one of ordinary skill in the art is readily able to make and use Claudin-7 for the practice of the claimed methods without undue experimentation. Applicant respectfully requests withdrawal of this rejection.

#### IV. Claim Amendments under 37 C.F.R. § 1.121

1. (Currently amended) A method of modulating angiogenesis and/or endothelial cell proliferation in a mammal comprising deliver[ing] to said mammal a composition comprising ~~at least on fragment, biological equivalent or derivative of~~ Claudin-7, wherein said ~~fragment, biological equivalent or derivative of~~ Claudin-7 modulates angiogenesis and/or endothelial cell proliferation.

2. (Currently amended) A method of modulating angiogenesis and/or endothelial cell proliferation in a mammal according to Claim 1 wherein said composition further comprises a physiologically acceptable vehicle.

3. (Currently amended) A method of reducing angiogenesis and/or endothelial cell proliferation in a mammal comprising deliver[ing] to said mammal a composition comprising ~~at least on fragment, biological equivalent or derivative of~~ Claudin-7, wherein said ~~fragment, biological equivalent or derivative of~~ Claudin-7 reduces angiogenesis and/or endothelial cell proliferation.

4. (Currently amended) A method of reducing angiogenesis and/or endothelial cell proliferation in a mammal according to Claim 3 wherein said composition further comprises a physiologically acceptable vehicle.

5. (Currently amended) A method of reducing tumor growth in a mammal comprising deliver[ing] to said mammal a composition comprising ~~at least on fragment, biological equivalent or derivative of~~ Claudin-7, wherein said ~~fragment, biological equivalent or derivative of~~ Claudin-7 reduces tumor growth.

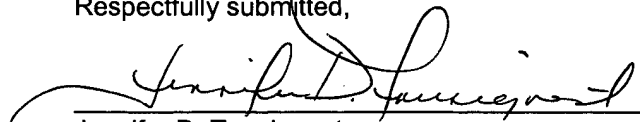
6. (Original) A method of reducing tumor growth in a mammal according to Claim 5 wherein said composition further comprises a physiologically acceptable vehicle.

## V. Conclusion

No fee is deemed necessary in connection with the filing of this communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 07-1074.

9/9/2004  
Date

Respectfully submitted,



Jennifer D. Tousignant  
Agent for Applicants  
Registration No. 54,498  
Telephone: (508) 270-2499  
Facsimile: (508) 872-5415

GENZYME CORPORATION  
15 Pleasant Street Connector  
P.O. Box 9322  
Framingham, Massachusetts 01701-9322